KJO
pISSN: 1011-8942 eISSN: 2092-9382
Korean J Ophthalmol 2020;34(6):439-445
https://doi.org/10.3341/kjo.2020.0042

Original Article

Visual Outcomes after Bilateral Implantation of an Extended Depth of Focus Intraocular Lens: A Multicenter Study

Moonjung Choi[1], Chan Young Im[2], Jin Ki Lee[3], Hyung-il Kim[4], Hyo Soon Park[5], Tae-im Kim[6]

[1]*Department of Ophthalmology, Konyang University Myunggok Medical Research Center, Konyang University College of Medicine, Daejeon, Korea*
[2]*Ian Eye Center, Seoul, Korea*
[3]*Department of Ophthalmology, Daegu Fatima Hospital, Daegu, Korea*
[4]*Gyeongju St. Mary's Eye Clinic, Gyeongju, Korea*
[5]*Nunevit Eye Center, Busan, Korea*
[6]*Department of Ophthalmology, Severance Hospital, Yonsei University College of Medicine, Seoul, Korea*

Purpose: To evaluate visual performance after bilateral implantation of an extended depth of focus (EDOF) intraocular lens (IOL).

Methods: This multicenter, prospective, observational study included 100 patients who underwent bilateral cataract surgery with a toric or non-toric EDOF IOL (Tecnis Symfony), and 96 patients completed the final assessment at 4 to 6 months. Binocular corrected distance visual acuity and uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA), and uncorrected near visual acuity (UNVA), spectacle independence, visual symptoms, and patient satisfaction were evaluated.

Results: Mean decimal visual acuity results showed a binocular corrected distance visual acuity of 1.10 ± 0.18, UDVA of 1.04 ± 0.17, UIVA of 0.96 ± 0.16, and UNVA of 0.68 ± 0.18. Binocular UDVA and UIVA were 0.8 (decimal) or better in 98% and 94% of patients, respectively. Binocular UNVA was 0.63 (decimal) or better in 76% of patients. Overall, 76% of the patients achieved spectacle independence across all distances, and more than 85% reported no or mild dysphotoptic phenomena. On a scale of 0 to 10, the median patient satisfaction score was 9 for far, 9.5 for intermediate, and 8 for near vision.

Conclusions: The Symfony EDOF IOL provided excellent distance, intermediate visual outcome, and functional near visual acuity. The visual results were associated with prominent levels of spectacle independence and patient satisfaction.

Key Words: Cataract, Multifocal intraocular lenses, Phacoemulsification, Presbyopia

With an increased demand for a spectacle-free lifestyle and technological advancements, cataract surgery with multifocal intraocular lens (IOL) implantation has become an effective solution for correcting presbyopia in patients who want to maintain their full range of vision.

Conventional bifocal IOLs use either refractive or diffractive optics to split the light and create two principal focal points, thus providing functional vision at a distance and up close [1]. This simultaneous imaging principle produces a sharp image overlaid by a secondary blurred, out-

Received: April 8, 2020 *Final revision:* August 28, 2020
Accepted: August 28, 2020

Corresponding Author: Tae-im Kim, MD, PhD. Department of Ophthalmology, Severance Hospital, Yonsei University College of Medicine, 50 Yonsei-ro, Seodaemun-gu, Seoul 03722, Korea. Tel: 82-2-2228-3570, Fax: 82-2-312-0541, E-mail: taeimkim@gmail.com

of-focus image, as such, these IOLs inherently produce a deterioration in contrast sensitivity and unwanted photic phenomena such as glare and halos [2]. Additionally, studies have reported insufficient intermediate vision with bifocal IOLs [3,4].

There is an increasing desire for spectacle independence at intermediate distances, especially due to the increased use of computers and smartphones. Trifocal IOLs were introduced to the market in 2010, and they provide an additional, third focal point to improve intermediate vision without compromising distance and near vision [5]. However, they are still vulnerable to decreased contrast sensitivity and photic phenomena due to the IOL's mechanism of splitting the light into discrete focal points [5].

An extended depth of focus (EDOF) technology was recently introduced to improve intermediate vision while maintaining image contrast. The diffractive echelette design, embedded on its posterior optical surface, extends the range of vision, and the achromatic technology reduces corneal chromatic aberrations to enhance retinal image quality and improve contrast sensitivity [6,7]. The elongated focus allows imaging in a continuous range of vision without overlapping near and far images, and therefore theoretically, provides a more consistent distance and intermediate vision with less dysphotopsia.

This multicenter study aimed to investigate the clinical outcome of patients bilaterally implanted with either the Tecnis Symfony or Tecnis Symfony toric extended range of vision IOLs (Johnson & Johnson Vision, Santa Ana, CA, USA) in terms of visual performance at different distances, spectacle independence, photic phenomena, and patient satisfaction.

Materials and Methods

Study design and patients

This 6-month, multicenter, prospective, noncomparative, observational study was conducted at five participating clinical sites in South Korea. It included patients who had uncomplicated cataract surgery with binocular implantation of either Symfony (ZXR00) or Symfony toric (ZXT) IOLs from June 2016 to June 2018. The non-toric Symfony IOL was implanted in eyes with a corneal astigmatism of less than 1.0 diopters (D). In cases of regular corneal astigmatism greater than 1.0 D, Symfony toric ZXT was recommended. Target refraction was emmetropia for all patients. Follow-up examinations were performed 1 day, 1 week, 4 to 8 weeks, and 4 to 6 months postoperatively.

The exclusion criteria included the presence of amblyopia, keratoconus, previous corneal or refractive surgery, chronic or recurrent uveitis, acute ocular diseases, previous ocular surgery, glaucoma, and any ocular diseases that could affect postoperative visual acuity.

This study was performed in accordance with the tenets of the Declaration of Helsinki and approved by the Severance Hospital Institutional Review Board, Seoul, South Korea (1-2016-0029). All patients provided written informed consent before study enrollment. The study was registered at the US National Institutes of Health (ClinicalTrials.gov) NCT03997890.

The IOL

The Tecnis Symfony IOL is a one-piece, ultraviolet-blocking, hydrophobic acrylic foldable lens with an overall length of 13 mm, an optic diameter of 6 mm, and a refractive index of 1.47. It incorporates a frosted edge design with a 360° posterior square edge. It has a biconvex, wavefront-designed anterior aspheric (-0.27 μm; model ZXR00) or toric-aspheric (model ZXT) surface to compensate for corneal spherical aberrations and a posterior achromatic diffractive surface to enhance contrast sensitivity. The echelette design allows a pattern of pupil-dependent light diffraction, which elongates the focal zone, resulting in an extended range of vision. It is available in spherical equivalent powers of 5.0–34.0 D in 0.5 D increments, and in five cylindrical powers: 1.00, 1.50, 2.25, 3.00, and 3.75 D (at the IOL plane).

Postoperative assessments

Binocular corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA) were assessed at 4 m using a Snellen chart. Binocular uncorrected intermediate visual acuity (UIVA) at 70 cm and binocular uncorrected near visual acuity (UNVA) at 40 cm were assessed using the Rosenbaum near vision card.

A subjective questionnaire on spectacle use, photic phenomena, and satisfaction was administered to all patients. Patients were asked how often (never, occasionally, 50% of

the time, frequently) they wear spectacles for near, intermediate, and distance activities. Nondirected and directed questions were used with regard to visual symptoms. Photic phenomena (halos, glare, and starbursts) were graded as none, trace, mild, moderate, or severe. Patients were asked to rate their level of satisfaction with distance, intermediate, and near vision on a scale from 0 (completely dissatisfied) to 10 (completely satisfied). Additionally, they were asked whether they would choose the same IOL again and if they would recommend the IOL to their friends and family. Surgeons were also asked to rate their level of satisfaction on a scale from 0 to 10 in terms of ease of manipulation and implantation of the IOL and the visual performance of the IOL.

Statistical analysis

Summary descriptive statistics were produced for all key variables of the study. Continuous variables were expressed as mean ± standard, and the percentage frequency was calculated for all categorical data.

Results

Patient demographics and refractive status

A total of 100 patients who underwent bilateral IOL implantation with either Symfony or Symfony toric IOLs were enrolled in this study. Ninety-six patients (192 eyes) completed the 4 to 6 months assessment and were included in the final analysis. The mean age was 61.19 ± 10.25 years, and 64.6% (62 patients) were women. The preoperative mean manifest refraction spherical equivalent (MRSE) was -0.57 ± 3.01 D. At the last postoperative visit after 4 to 6 months, the MRSE was -0.41 ± 0.44 D. The postoperative spherical equivalent was within 0.50 D in 72.4% of eyes, and 90.6% of eyes had less than 1.00 D of residual cylinder.

Eleven patients (11.5%) received the toric Tecnis Symfony IOL in both eyes, and one patient (1.0%) had a mixed implantation of Symfony and Symfony toric IOLs. The mean age of patients who received the toric version in at least one eye was 54.75 ± 10.99 years, and 58.3% (seven pa-

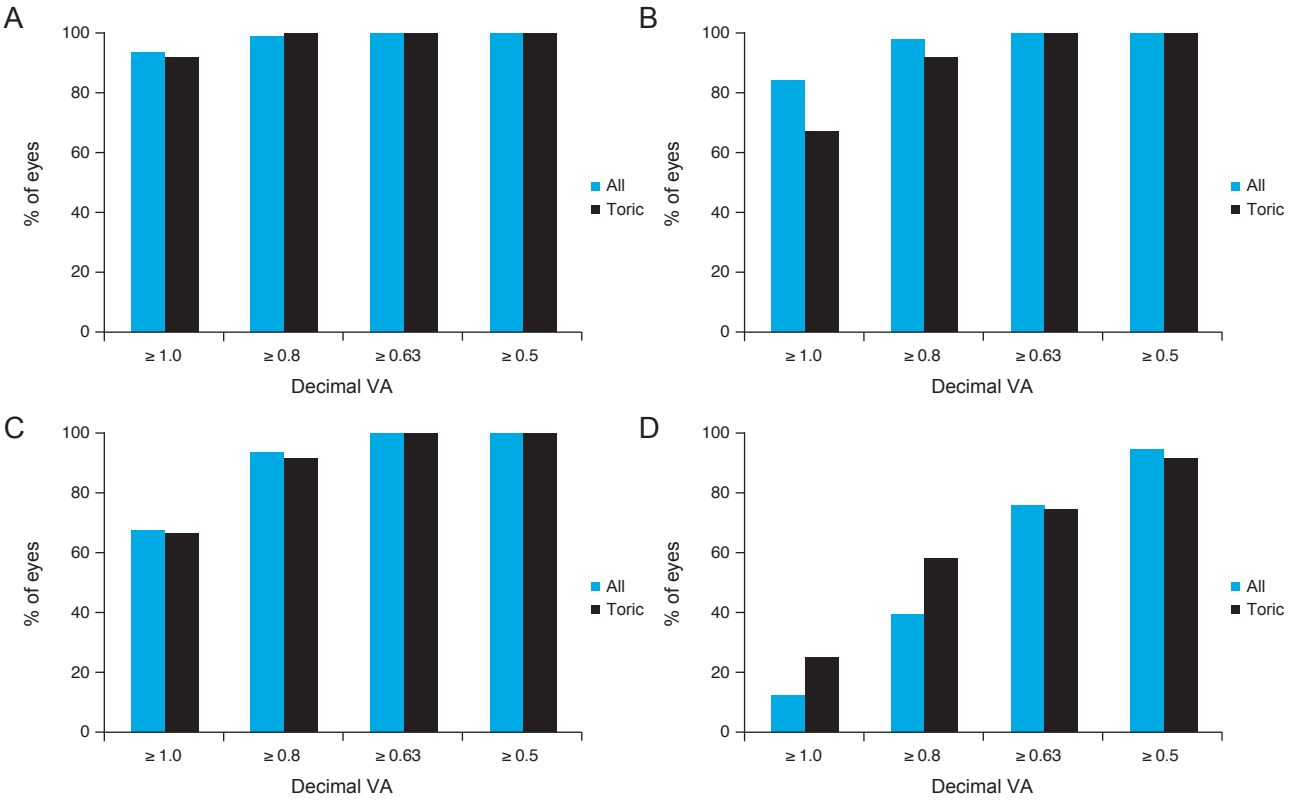

Fig. 1. Cumulative binocular visual acuity. (A) Corrected distance visual acuity (VA), (B) uncorrected distance VA, (C) uncorrected intermediate VA, and (D) uncorrected near VA.

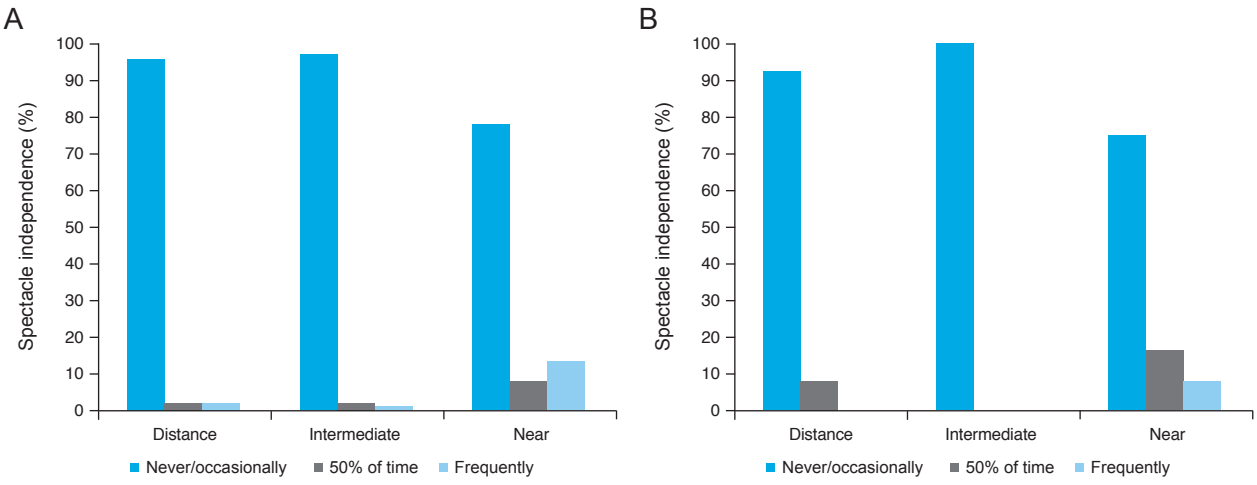

Fig. 2. Spectacle independence of (A) all patients and (B) patients implanted with toric intraocular lens.

tients) were women. The preoperative MRSE was -1.99 ± 3.57 D, and the postoperative MRSE at 4 to 6 months was -0.46 ± 0.41 D.

Visual outcome

In all patients, the mean binocular CDVA was 1.10 ± 0.18 (-0.04 ± 0.07 logarithm of the minimum angle of resolution [logMAR]) and mean binocular UDVA was 1.04 ± 0.17 (-0.02 ± 0.07 logMAR). Mean binocular UIVA and UNVA were 0.96 ± 0.16 (0.04 ± 0.07 logMAR) and 0.68 ± 0.18 (0.17 ± 0.14 logMAR), respectively.

In patients with toric Symfony IOLs in at least one eye, the mean binocular CDVA was 1.09 ± 0.18 (-0.04 ± 0.07 logMAR); mean binocular UDVA was 1.00 ± 0.20 (0.00 ± 0.09 logMAR); mean binocular UIVA was 0.92 ± 0.12 (0.04 ± 0.06 logMAR); and mean binocular UNVA was 0.74 ± 0.18 (0.13 ± 0.12 logMAR).

The cumulative percentages of patients reaching various visual acuity levels across different distances are shown in Fig. 1A-1D.

Spectacle independence

Overall, 76% of all patients and 75% of toric patients never or only occasionally used spectacles across all distances. Regarding distance vision, 96% of all patients and 92% of toric patients stated that they never or only occasionally needed glasses (Fig. 2A, 2B). For intermediate tasks, 3.1% of all patients required spectacles most of the time, whereas all the toric patients were completely spectacle independent. In total, 13.5% of all patients and 8.3% of the toric patients frequently needed reading glasses (Fig. 2A, 2B).

Photic phenomena

On nondirected questioning, 23.0% of patients said that they had some dysphotopsia. Overall, 92.0%, 89.4%, and 86.7% of all patients, and 91.7%, 91.7%, and 83.3% of the toric patients reported no or minimal halo, glare, and starburst, respectively (Fig. 3A, 3B).

Patient and surgeon satisfaction

The median score for patient satisfaction was 9.0 (range, 5–10) for distance, 9.5 (range, 6–10) for intermediate, and 8.0 (range, 1–10) for near vision (Fig. 4). The median score for toric patients was 9.0 for distance (range, 7–10) and intermediate (range, 6–10), and 7.0 for near vision (range, 4-10) (Fig. 4). In total, 81.25% of patients were willing to recommend the IOL to friends and family, and 80.21% said that they would choose the same IOL again. The overall surgeon satisfaction was high with a median score of 9.0 (range, 6–10), and all other criteria, including implantation and handling of the IOL, achievement of target refraction, and visual performance, reached a median score of 9.0 (range, 6–10).

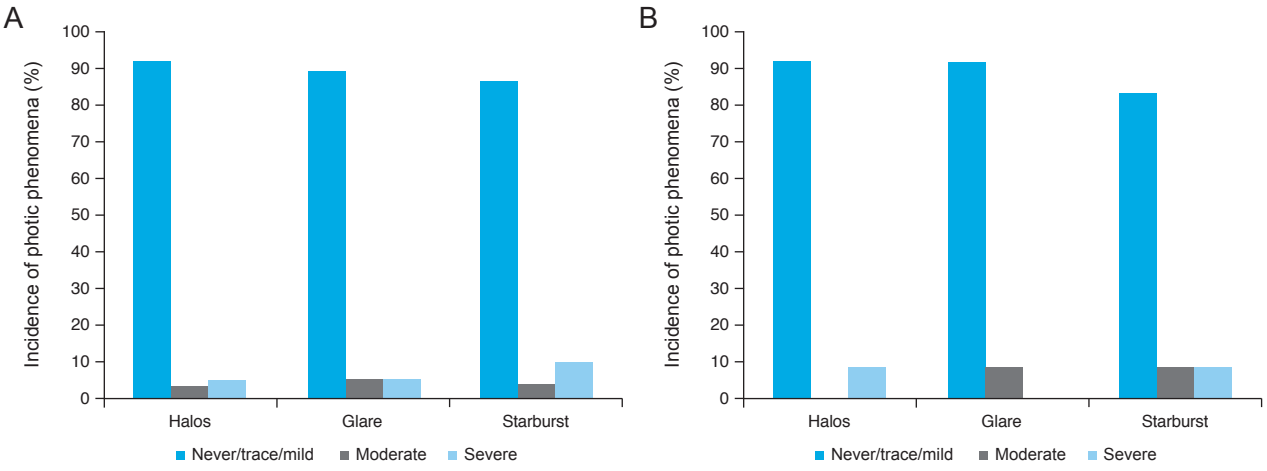

Fig. 3. Incidence of photic phenomena of (A) all patients and (B) patients implanted with toric intraocular lens.

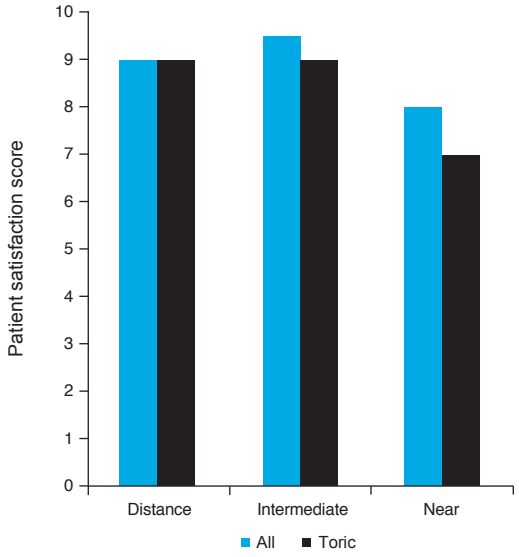

Fig. 4. Patient satisfaction score regarding distance, intermediate, and near vision.

Complications and adverse events

One patient had macular edema in the right eye and was treated with posterior subtenon triamcinolone injection, after which the eye fully recovered. Refractive touch-up treatment was performed in five eyes of five patients. There was no incidence of IOL decentration or tilt.

Discussion

The introduction of various multifocal IOLs has offered surgical options for correcting presbyopia in cataract patients who want spectacle independence in daily routine activities. The selection of an IOL depends on the patient's characteristics, preferences, lifestyle, job, and vision expectations. Intermediate vision is becoming more important for working life and daily activities because of the increased use of computers, tablets, and smartphones.

Bifocal IOLs with a low or moderate near addition may help to improve intermediate vision at the expense of near vision, whereas trifocal IOLs offer an additional focus for intermediate vision [8]. However, the principle of multifocality, in which the image is only sharp within a limited zone around the foci, means that the vision between the foci remains blurred. The EDOF IOL allows for a continuous range of vision and provides a consistent visual performance from far to intermediate distance. Due to the elongated focus, this IOL is also less susceptible to errors in power calculation or the final position of the IOL, and distance vision is quite well preserved despite minimal refractive error or remaining astigmatism [9]. In fact, our study showed that bilateral implantation of an EDOF lens provided excellent binocular uncorrected distance visual acuity despite a mean postoperative refractive error of -0.41 D. The mean decimal UDVA was 1.04 (-0.02 logMAR) and 97.92% of the patients achieved 0.8 (0.1 logMAR) or better. This result was similar or superior to that of previous studies [6,7,10,11]. Pedrotti et al. [7] reported a mean binocular UDVA of 0.08 (logMAR). A previous study that compared Tecnis Symfony with two trifocal IOLs reported a mean binocular UDVA of 0.833 (0.08 logMAR), which was comparable to trifocal IOLs [10]. One study that compared the Symfony IOL with a trifocal IOL

showed that the Symfony IOL had better distance visual acuity [12]. Another study on the Symfony IOL reported a UDVA of 0.03 (logMAR) [11]. The mean UDVA of the non-monovision group in the multicenter study was 0.95, which was similar to 0.94 in the monovision group of the same study [6]. This shows that the residual refractive error does not significantly reduce uncorrected distance vision after EDOF IOL implantation. Another study stated that the Symfony EDOF IOL showed better uncorrected distance and intermediate visual outcomes and higher spectacle independence than the monofocal IOL and +3.0 D multifocal IOL [13]. In our study, Symfony EDOF IOLs also showed excellent intermediate visual acuity (VA) with a mean binocular UIVA of 0.96 (0.02 logMAR) and 93.75% of patients achieved 0.8 (0.1 logMAR) or better. Patient satisfaction was highest for intermediate vision. Previous studies reported comparable intermediate VA of 0.79 and 0.99 at the same distance of 70 cm [6,14]. This shows that the Symfony IOL provides superior VA across intermediate and far distances.

The mean UNVA was 0.68 (0.17 logMAR) in our study, which was lower than the intermediate and distance VA. This result is consistent with those of previous studies with Symfony IOLs targeting postoperative emmetropia [10,11,13]. However, 76.04% of the patients achieved an UNVA of 0.63 (0.2 logMAR) or better, which may be sufficient to provide functional vision for near tasks. Since this EDOF IOL provides an elongated focus and has no near addition, there is inevitably a theoretical loss of near vision. The extended range of focus may contribute to near visual function to some extent, as shown by a previous study that showed better near VA of Symfony IOLs compared to monofocal IOLs or the +2.5 D multifocal IOL [7,13], but this may not be as efficient as a near addition. In fact, another study showed that the trifocal IOL exhibited better UNVA than the Symfony IOL [12]. Accordingly, our study showed that more patients needed glasses for reading compared to far or intermediate distances. Previous studies have also acknowledged this limitation and suggested that this can be overcome with micromonovision [6,15].

More than 85% of our patients reported no or only mild halos, glare, or starbursts. This was similar to a study in which more than 90% reported no or mild photic phenomena [6]. Previous studies reported no significant difference in photic phenomena between Symfony EDOF and monofocal IOLs [7,13]. Although some other studies reported a much lower incidence of nighttime visual disturbances, such as less than 1% [10], the difference is likely due to differences in questioning methods and lack of standardization in detecting visual symptoms. There were no cases of IOL explantation due to visual discomfort or dissatisfaction, and overall patient satisfaction was high, suggesting that visual symptoms likely had little or no impact on their daily activities.

Five patients received postoperative refractive touch-up treatment. Three patients received laser enhancement for residual myopia and reached UDVA and UIVA of 0.8 (0.1 logMAR) or more and UNVA of 0.63 (0.2 logMAR) or more. Two patients underwent hyperopic correction and reached UDVA and UIVA of 0.8 (0.1 logMAR) or more and UNVA of 0.5 (0.3 logMAR) or more. All patients experienced better visual acuity across all distances and higher satisfaction after laser enhancement treatment.

The limitations of this study include the difference in the methods of outcome measurement in terms of visual acuity and questionnaire on visual symptoms, which limits direct comparison with findings of previously published studies. In addition, this study included results of only EDOF IOL and was not directly compared with other types of IOL. The outcomes regarding photic phenomena and spectacle independence were self-reported and were at risk of recall bias. In addition, only binocular VA was measured instead of both monocular and binocular VA. However, we think that binocular summation better reflects the circumstances in which a person usually functions.

The Symfony EDOF IOL demonstrated excellent distance, intermediate visual performance, and functional near visual acuity. The visual results were associated with prominent levels of spectacle independence and patient satisfaction. Therefore, the Symfony IOL may be considered a promising option for cataract patients who want to achieve a consistently high quality of vision across far and intermediate distances.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Acknowledgements

This research was supported by a grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI) funded by the Ministry of Health & Welfare, Republic of Korea (grant no. HI18C1111), and by the Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (NRF-2019R1F1A1062468).

References

1. Lane SS, Morris M, Nordan L, et al. Multifocal intraocular lenses. *Ophthalmol Clin North Am* 2006;19:89-105.
2. Alba-Bueno F, Vega F, Millan MS. Halos and multifocal intraocular lenses: origin and interpretation. *Arch Soc Esp Oftalmol* 2014;89:397-404.
3. Alfonso JF, Fernandez-Vega L, Amhaz H, et al. Visual function after implantation of an aspheric bifocal intraocular lens. *J Cataract Refract Surg* 2009;35:885-92.
4. Alfonso JF, Puchades C, Fernandez-Vega L, et al. Visual acuity comparison of 2 models of bifocal aspheric intraocular lenses. *J Cataract Refract Surg* 2009;35:672-6.
5. Gatinel D, Pagnoulle C, Houbrechts Y, Gobin L. Design and qualification of a diffractive trifocal optical profile for intraocular lenses. *J Cataract Refract Surg* 2011;37:2060-7.
6. Cochener B; Concerto Study Group. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. *J Cataract Refract Surg* 2016;42:1268-75.
7. Pedrotti E, Bruni E, Bonacci E, et al. Comparative analysis of the clinical outcomes with a monofocal and an extended range of vision intraocular lens. *J Refract Surg* 2016;32:436-42.
8. Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, et al. Optical quality differences between three multifocal intraocular lenses: bifocal low add, bifocal moderate add, and trifocal. *J Refract Surg* 2013;29:749-54.
9. Akella SS, Juthani VV. Extended depth of focus intraocular lenses for presbyopia. *Curr Opin Ophthalmol* 2018;29:318-22.
10. Cochener B, Boutillier G, Lamard M, Auberger-Zagnoli C. A comparative evaluation of a new generation of diffractive trifocal and extended depth of focus intraocular lenses. *J Refract Surg* 2018;34:507-14.
11. Attia MS, Auffarth GU, Kretz FT, et al. Clinical evaluation of an extended depth of focus intraocular lens with the Salzburg reading desk. *J Refract Surg* 2017;33:664-9.
12. de Medeiros AL, de Araujo Rolim AG, Motta AF, et al. Comparison of visual outcomes after bilateral implantation of a diffractive trifocal intraocular lens and blended implantation of an extended depth of focus intraocular lens with a diffractive bifocal intraocular lens. *Clin Ophthalmol* 2017;11:1911-6.
13. Pedrotti E, Carones F, Aiello F, et al. Comparative analysis of visual outcomes with 4 intraocular lenses: monofocal, multifocal, and extended range of vision. *J Cataract Refract Surg* 2018;44:156-67.
14. Sachdev GS, Ramamurthy S, Sharma U, Dandapani R. Visual outcomes of patients bilaterally implanted with the extended range of vision intraocular lens: a prospective study. *Indian J Ophthalmol* 2018;66:407-10.
15. Ganesh S, Brar S, Pawar A, Relekar KJ. Visual and refractive outcomes following bilateral implantation of extended range of vision intraocular lens with micromonovision. *J Ophthalmol* 2018;2018:7321794.